

Remarks

Claims 1-6, 8-64 and 73-79 are pending in the application. Claims 65-72 stand withdrawn from consideration. Claims 11-6, 8-64 and 73-79 have been rejected. Reconsideration is respectfully requested in view of the above changes and the following remarks.

Response to 35 U.S.C. 102 and 103 Rejections – DeSushko

Claims 1-6, 8-15, 18-21, 26-29, 32-48, 53-56, 58, 61 and 64 have been rejected as allegedly anticipated by DeSushko. As to claim 1, Examiner alleges that DeSushko removing flaps 13 and 14 correspond to applicants' non-meltable base member, that DeSushko tube 10 corresponds to applicants' non-meltable reinforcement, and that applicants' meltable portion formed around the length of the reinforcement corresponds to DeSushko medicament 15. Examiner alleges that flaps 13 and 14 have a width greater than the width of the medicament.

Without acquiescing in the rejection, and in an effort to advance prosecution, claims 1 and 61 have been amended to more particularly point out and define the invention. The amended claims point out that meltable portion of an embodiment of applicants' device, which is formed along the length of the non-meltable reinforcement, has a diameter which tapers from the reinforcement second end to the reinforcement first end. The reinforcement first end is the end of the reinforcement attached to the base. The reinforcement second end is the distal end of the reinforcement. According to *Webster's New Collegiate Dictionary*, G. & C. Merriam Company, 1977, p. 1192, the word "tapered" means to become progressively smaller toward one end. Thus, the device of this embodiment has a meltable portion the diameter of which tapers toward the reinforcement first end and the base. This embodiment is shown in Figures 2 and 3, and described at page 12, lines 15-17.

Even assuming *arguendo* that DeSushko's medicament 15 can be regarded as meltable and that flaps 13 and 14 can be regarded as a non-meltable reinforcement (applicants assert that they can not), the only portion of the DeSushko medicament body which may be considered tapered is the portion around the bulge marked 12 in DeSushko. The rest of the length of medicament 15, from the bulge 12 to the tube 10 distal end, has a constant diameter. As a result,

DeSushko does not disclose a device having a meltable portion formed around the length of a reinforcement, whereby the meltable portion has a diameter which tapers from the distal end of a reinforcement to the base.

It is respectfully submitted that DeSushko does not anticipate claims 1 and 61, and their dependent claims 2-6, 8, and 10-32, 62-64, 73 and 74.

The same tapered meltable portion feature is set forth in amended claims 3 and 9. DeSushko does not anticipate claims 3 and 9.

Claims 33 and 35 define another embodiment of the invention wherein a non-meltable reinforcement comprises a first end attached to a non-meltable base and a second end distal from the base. The use of the device is claimed in claim 76. The reinforcement comprises a urethral segment extending from the first end and a bladder segment extending from the urethral segment, terminating in the reinforcement second end. The bladder segment is contained substantially entirely in the bladder; the urethral segment is contained substantially entirely in the urethra. A meltable portion, formed around the entire length of the reinforcement, is characterized by a taper region formed around the reinforcement urethral segment, and an extension region formed around the reinforcement bladder segment. In the taper region, the meltable portion has a diameter which tapers toward the reinforcement first end. See Figure 4.

The alleged DeSushko reinforcement, tube 10, is not characterized by a segment contained substantially entirely in the urethra and a distal segment contained substantially entirely in the bladder. There is no indication in DeSushko that any part of the bougie is adapted to extend into the bladder. There is no part of the DeSushko device that corresponds to applicants' meltable portion taper region which extends the length of the part of the reinforcement which is contained in the urethra. In DeSushko, the only part of the disclosed bougie which tapers is the small region proximal to the maximum diameter of bulge 12. This is only a small portion of the part of the bougie that extends into the urethra. The remaining urethra-penetrating part of the DeSushko device, which constitutes the bulk of the length of the device, is not tapered, or is tapered the wrong way (the region distal to the maximum diameter of bulge 12). Thus, DeSushko does not anticipate claims 33, 35 or 76, nor their dependent claims 34, 36-60 and 77-79.

The device of each of the aforementioned claims is also not obvious over DeSushko. The tapered shape of applicants' device cooperates with the distinctive pressure profile generated within the female urethra lumen by the periurethral musculature to retain the suppository within the urethra. There is nothing in the disclosure of DeSushko suggesting this shape. Indeed, there would have been no incentive to adopt this tapered shape since DeSushko is directed to a male urethral device. While there is a tangential reference at col. 2, lines 90-94 that the device "may be used for treatment either with the male or the female", the entire disclosure of DeSushko focuses on the male anatomy. All anatomical references are made to male tissue or organs. The *fossa navicularis* (page 2, lines 13, 28) is unique to the male anatomy, as are the Cowper's and prostate gland (page 2, lines 31-32). The anatomy of the female urethra is very different from the male (as described in WO 01/13721, incorporated by reference into the present specification at page 11, lines 6-7). If inserted into the female urethra, the bulge 12 of DeSushko would likely function to either push the suppository out of the urethra or into the urethra depending on its position relative to the periurethral musculature, a concern not realized in the male urethra. There is nothing in the disclosure of DeSushko that would have suggested to one of ordinary skill in the art to taper the shape of the suppository, to take advantage of the female periurethral musculature's force profile to retain the suppository within the urethra.

The urethral suppository of claims 1, 3, 9, 33 and 35, the methods of claims 61 and 76, and the embodiments defined in the various dependent claims, are neither anticipated nor obvious in view of over DeSushko.

Claims 3 and 35, and their dependent claims 4 and 36 are distinguished from DeSushko for yet other reasons. These claims recite a non-meltable base member which is an ellipsoid having a major axis substantially perpendicular to the longitudinal axis of the reinforcement. Examiner incorrectly alleges that DeSushko bulge 12 satisfies this feature.

Examiner's characterization of bulge 12 as corresponding to applicants' non-meltable base (Detailed Action, page 8, next-to-last par.) is inconsistent with Examiner's earlier characterization of DeSushko flaps 13 and 14 as the "base" (page 7, 1st par.). Clearly, the DeSushko device can not have two bases. In any event, a complete reading of the claims in

question establishes that bulge 12 can not correspond to applicants' non-meltable base claim element.

According to claims 3 and 35, a non-meltable base member is provided which *is not for insertion into the urethra*. According to DeSushko, bulge 12 rests on the *fossa navicularis* to resist undue outward movement of the bougie from the urethra (page 2, lines 93-95). The *fossa navicularis* in the male is the enlargement of the distal penile urethra proximal to the urethral meatus (the external urethral orifice). "Fossa navicularis", *Wikipedia, The Free Encyclopedia* (http://en.wikipedia.org/wiki/Fossa_navicularis, downloaded Feb. 23, 2006) (attached). As an enlargement of the urethra, the *fossa navicularis* it is therefore contained *in* the urethra. Bulge 12 thus rests in the urethra, and therefore can not correspond to applicants' non-meltable base member, which *is not for insertion into the urethra*. DeSushko does not anticipate claims 3 and 35, and their dependent claims 4 and 36.

Claims 5, 6, 37, and 38 recite a device where the base member is grooved. Examiner alleges that blade 11' of DeSushko Fig. 6 is such an element. Examiner's characterization of blade 11' as corresponding to applicants' non-meltable base is inconsistent with Examiner's earlier characterization of DeSushko flaps 13 and 14 as the "base" (page 7, 1st par.). The DeSushko device can not have two bases. In any event, blade 11' does not correspond to applicants' non-meltable base.

The base claims from which claims 5, 6, 37, and 38 depend recite a non-meltable base member from which a non-meltable reinforcement projects. The base member *is not for insertion into the urethra*. DeSushko blade 11' is a spirally arranged blade which bears medicament and surrounds tube 18. Blade 11' does not function as a base member. Moreover, even assuming *arguendo* that DeSushko tube 18 can be characterized as a "reinforcement" (which is not admitted), it does not project from blade 11'. The claims require a reinforcement projecting from a base. Tube 18 is surrounded by blade 11', and therefore does not project from blade 11'. Moreover, blade 11' becomes inserted into the urethra, and is therefore not characterized as "not for insertion into the urethra" as required by the instant claims. Rather, blade 11' extends the entire length of the DeSushko Fig. 6 device, and clearly becomes inserted into the urethra.

Examiner alleges that as to claims 8 and 40, the feature that the base member is comprised of a polymer, is satisfied by DeSushko page 1, lines 75-81. In the paragraph immediately preceding the rejection of claims 8 and 40 (Detailed Action, p. 7, 2nd par.), Examiner alleges that the DeSushko structure corresponding to applicants' base member is the set of flaps 13 and 14. While the flaps are mentioned in the referenced disclosure from DeSushko page 1, lines 75-81, there is no indication of the material from which they are formed. The only recitation of a structural material in the referenced disclosure is a description of tube 10 being "preferably flexible and preferably made from a very thin rubber". Thus, the referenced disclosure does not, as Examiner alleges, teach a base that is comprised of a polymer.

Examiner alleges, as to claims 11 and 42, that the alleged "reinforcement" of DeSushko, tube 10, "comprises a rod". Without admitting that tube 10 is a reinforcement, applicants point out that a tube can not be a rod, since a tube is hollow, and a rod is solid. This is emphasized by the clarifying amendment to claims 11 and 42, that the rod is *solid* (specification, page 17, lines 9-12). A solid rod can not be employed by DeSushko. Tube 10 must be hollow so as to permit "natural urinary functions", as required by DeSushko at page 1, lines 18-19, and 83-84. Tube 10 must be hollow to permit urination.

Examiner alleges that as to claim 15, "the second end of the reinforcement (10) extends outside the meltable portion". The Examiner alleges that the "second end is considered to be a distal portion of 14 and 15, and the base member is considered to be the proximal portion of 14 and 15".

It is respectfully submitted that Examiner has misidentified the flaps 13 and 14, earlier alleged to be a base member, as elements "14 and 15". Element 15 is medicament. The flap members are elements 13 and 14.

The "second end" of the reinforcement which extends outside the suppository meltable portion according to claim 15 is the end of the reinforcement distal from the base. If DeSushko tube 10 is construed as a reinforcement (which is not admitted), the end corresponding to applicants' second end is the end of tube 10 which is proximal to tip 16. Tube 10 is not shown as extending past medicament 15 in any of the drawings of DeSushko. This feature is simply not disclosed by DeSushko.

Examiner alleges, as to claims 26-29 and 53-56, that DeSushko discloses “helical grooves (11) to retain the suppository inside the urethra”, as allegedly described at col. 2, lines 5, and 54-56). The claims in issue state that the grooves are formed in the meltable portion of applicants’ device. The alleged “grooves” of element 11, even if they may be construed as grooves, are not formed in any meltable portion of the DeSushko device. Element 11 is a spiral blade surrounding tube 10. The blade is clearly non-meltable, since its function is to retain the medicament. DeSushko does not disclose a urethral suppository comprising a meltable portion having grooves.

Claims 16, 17, 24, 25, 30, 31, 51, 52, 57, 59, 60, 62, 63 and 73-79 have been rejected for obviousness over DeSushko.

Examiner admits that DeSushko does not teach the suppository dimensions of claims 16, 17, 25, 30, 31, 51, 52, 57, 59, 60, and 73-75, but alleges that the dimensions as optimum or workable ranges thus involving only routine skill in the art. Each rejected claim depends directly or indirectly from claim 1 or 33. For the reasons set forth above, claims 1 and 33 are allowable over DeSushko. In view of the allowability of claims 1 and 33, dependent claims 16, 17, 25, 30, 31, 51, 52, 57, 59, 60, and 73-75 are similarly allowable.

The device of 16, 17, 25, 30, 31, 51, 52, 57, 59, 60, and 73-75 is further distinguished over DeSushko in that the recited dimensions are dimensions relevant to the female anatomy. DeSushko describes a device specially adapted for the male anatomy.

As to claim 61 (and therefore its dependent claims 62-64 also) Examiner correctly points out that DeSushko does not teach a base member that is *not for insertion into the urethra*, but alleges that it would have been obvious to secure the DeSushko boogie by adhesive on members “14 and 15” (presumably members 13 and 14, since “15” is the medicament in DeSushko) such that the members would not inset into the urethra. Applicants respectfully disagree that the DeSushko device can be used in this manner in a female. The urethral *os* (opening) in the female is located in the labia. The labia is surrounded by a mucous surface, making the use of adhesive flaps impractical. While an adhesive might be capable of adhering to the flesh of the male anatomy, it would not be effective in a female. In any event, for the reasons set forth previously, the device utilized in the method of claim 61 is not obvious over DeSushko.

As to claim 76 (and therefore its dependent claims 77-79 also) Examiner admits that DeSushko does not teach a device with a reinforcement that extends into the bladder. The Examiner alleges that this feature would however have been obvious from DeSushko because DeSushko allegedly teaches that his device can be used to deliver medication to the bladder, citing page 2, lines 45-50. The referenced disclosure indicates that the bladder, which may become diseased, is located adjacent the internal urinary meatus, and that the bougie affords a means for medicament around the affected part "when in this region". The latter phrase does not indicate that the bougie extends into the bladder. In fact, the opposite is understood from the disclosure of DeSushko. Page 2, lines 32-33, indicates that the bougie reaches the internal urinary meatus. This structure is adjacent to, but not within, the bladder. There is nothing to suggest that the bougie extends past the internal urinary meatus into the bladder. In any event, for the reasons set forth previously, the device utilized in the method of claim 76 is not obvious over DeSushko.

Claims 22, 23, 49, 50, 62, 63, 77, 78 have been rejected as allegedly obvious over DeSushko, or DeSushko in combination with other references. Each claim depends from an independent claim which is believed patentable, for the reasons discussed above. The dependent claims recite additional features of applicants' device and method which further distinguish over the asserted prior art. In view of the allowability of the independent base claims, claims 22, 23, 49, 50, 62, 63, 77, 78 are likewise believed allowable.

Response to Obviousness-Type Double Patenting Rejection

Claims 1-6, 8-21, 23-25, 32-48, 50-53, 60-64 and 73-79 have been rejected for alleged obviousness-type double patenting over claims 1-21 of U.S. Patent 6,464,670 ('670 Patent) in view of DeSushko. Claims 22 and 49 have been rejected on the same basis, further in view of Jackson *et al.*

A rejection for obviousness-type double patenting is appropriate where the claimed subject matter is not patentably distinct from the subject matter *claimed* in a commonly owned patent. The inquiry must focus on the claims of the allegedly conflicting patent. "An obviousness-type double patenting rejection should make clear: (A) The differences between the

inventions defined by the conflicting claims – a claim in the patent compared to a claim in the application; and (B) the reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim at issue would have been an obvious variation of the invention defined in a claim in the patent”. MPEP 804 II.B.1. “When considering whether the invention defined in the claims of an application would have been an obvious variation of the invention defined in the claims of a patent, the disclosure of the patent may not be used as prior art.” *Id.*

The Examiner’s double-patenting rejection is erroneously premised on the disclosure of the ‘670 Patent, and does not refer to the *claims* of the allegedly conflicting ‘670 Patent. The rejection states: “Patent ‘670 *teaches* urethral suppository”. What the ‘670 Patent teaches is irrelevant since a double patenting rejection must be based upon the claims. When considering applicants’ dependent claims, Examiner states: “As to the following claims [of the pending application], Patent ‘670 *teaches* the limitations as follows.” This remark is then followed by numerous references to the specification of the ‘670 Patent that allegedly support the double patenting rejection.

The correct test for double patenting here is not whether it would have been obvious to modify the device disclosed by the ‘670 Patent in view of DeSushko but whether a person of ordinary skill in the art would conclude that the invention defined in the present claims would have been an obvious variation of the invention defined in a claim in the ‘670 Patent. MPEP 804 II.B.1. Examiner has failed to sustain that burden. Notwithstanding the incorrect formulation of the double patenting rejection, applicants will respond to the substance of the rejection in order to advance prosecution.

The claimed invention of the ‘670 Patent is directed in one aspect (claim 1) to a urethral suppository formed from a meltable biocompatible material comprising a shaft having a first end and tapering toward a second end, and a knob extending from the shaft second end. The knob is sized to prevent insertion thereof into the urethra. The suppository comprises at least one therapeutic agent. The ‘670 Patent claims differ from the present claims in at least the following respects. The ‘670 Patent claims do not specify a non-meltable base member not for insertion into the urethra. The ‘670 Patent claims do not specify a non-meltable reinforcement attached to such a base member. Examiner alleges that these features are disclosed in DeSushko, and that it

would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of the '670 Patent to provide the tube and bulge of DeSushko. The alleged incentive for the modification is that DeSushko allegedly teaches the advantage of the tube as serving as a retaining member for medicament and the bulge to retain the device in the body. Applicants respectfully disagree.

One of ordinary skill in the art would not have concluded that the invention of the present claims is an obvious variant over any of the claims of the '670 Patent, notwithstanding the teachings of DeSushko. Examiner considers the assembly of DeSushko's tube 10 and partition-forming members 25 and 26 as applicants' claimed non-melttable reinforcement. Tube 10 is not for reinforcing the DeSushko bougie. The purpose of tube 10 is to serve as a conduit for urine. Unlike the device of the present invention (and the device of the '670 Patent), the DeSushko device is intended not only to deliver medicament, but also allow the user to urinate when the bougie is in place in the urethra. Indeed, it is the stated object of DeSushko to permit retention of medicament in the urethra as long as desired, "permitting, at the same time, the natural urinary functions" (page 1, lines 17-19). There is nothing in the disclosure of DeSushko that indicates that the tube performs a reinforcing function. Indeed, the bougie is designed to "be so flexible so as to conform to the contour of the parts with which used, and which may be retained in the urethra, for a considerable length of time without *irritation or undesirable effects on the patient*" (page 1, lines 35-37; emphasis added). The bougie is designed to be "flexible and elastic" ((page 1, line 42). The tube is preferably made of "a very thin rubber" (page 1, line 77). DeSushko states: "By having the tube flexible, it will accommodate itself to various conditions which may be required, while at the same time, causing little, if any, inconvenience to the parts being treated" (page 2, lines 40-44). The reason for the flexibility is clear. Notwithstanding DeSushko's suggestion that his device may be used for treatment of males or females, the bougie is designed for the male anatomy. A reinforced device which is not flexible would be extremely painful to the male wearer, and would grossly irritate the penis. A reinforced device would therefore be in direct conflict with the object and teachings of DeSushko.

DeSushko states at page 2, lines 80-83 that the "retaining members" (partition members 25 and 26, for retaining medicament) serve "to reinforce the tube and prevent its undue

collapse”. However, there is nothing in the disclosure that suggests that preventing the collapse of the tube has any reinforcing effect on the bougie as a whole, and does not suggest that the combination of tube 10 and partition members 25 and 26 has any reinforcing effect on the bougie. Indeed, as noted by Examiner, the principal function of members 25 and 26 is to retain medicament. Retention of medicament is not reinforcement of the structure of the bougie. The DeSushko bougie must be at all times flexible, for the reasons indicated above.

There would have been no incentive to the skilled artisan to modify the claimed device of the ‘670 Patent to introduce the tube 10 and partition-forming members 25 and 26 of DeSushko. The urethral suppository of the ‘670 Patent is essentially a solid device, which rapidly melts to release drug to the urethra. The biocompatible material from which the device is formed is selected to be capable of liquefaction within a relatively short period of time. There would have been no incentive to modify the device to provided a tube for permitting urination, which would only be required for an extended wear device. There is nothing in the claims of the ‘670 Patent which would suggest that the device should or could be modified by insertion of a tube to permit urination by the wearer while the device is in place. Even if there was an incentive to make this modification, the resultant would not be the claimed invention. The flexible tube of DeSushko, either alone or in combination with partition members 25 and 26, is not a reinforcement. Clearly, the instant claims are not directed to mere obvious variations of inventions claimed in the ‘670 Patent, even when the disclosure of DeSushko is considered.

Examiner alleges that the bulge 12 in tube 10 of DeSushko is considered applicants’ non-meltable base. The complete claim element is “a non-meltable base member not for insertion into said urethra”. As indicated above, Examiner’s characterization of bulge 12 as corresponding to applicants’ non-meltable base is inconsistent with Examiner’s earlier characterization of DeSushko flaps 13 and 14 as the “base” (page 7, 1st par.). In any event, bulge 12 can not correspond to applicants’ non-meltable base claim element. The claimed base member is *not for insertion into the urethra*. As discussed above, DeSushko bulge 12 is designed to rest on the *fossa navicularis* to resist undue outward movement of the bougie from the urethra (page 2, lines 93-95). The *fossa navicularis*, and therefore bulge 12, are contained *in* the urethra. Bulge 12 can not correspond to applicants’ non-meltable base member, which is *not for insertion into the*

urethra. Thus, even if the device of the '670 Patent claims could be modified to insert tube 10 and its bulge 12, the result would not be the presently claimed invention. The alleged element corresponding to applicants' non-meltable base member would reside inside the urethra, which is the exact opposite of what is claimed. DeSushko does not establish that the instant claims are a mere obvious variation of any invention claimed in the '670 Patent.

Moreover, there would have been no incentive to modify the device of the '670 Patent claims to include a tube with a bulge positioned to rest in the *fossa navicularis* to resist undue outward movement of the bougie from the urethra (page 2, lines 93-95). The *fossa navicularis* is the enlargement of the distal *penile* urethra proximal to the urethral meatus. The *fossa navicularis* is unique to the male anatomy. The device of the '670 Patent is designed as a urethral suppository for delivering therapeutic agent to structures of the female anatomy. The '670 device (and the device of the present invention, for that matter), are shaped to take advantage of the pressure profile generated by the female periurethral musculature to retain the suppository within the female urethra. There would have been no incentive for one skilled in the art to modify the *female* urethral suppository of the '670 Patent claims to add a feature designed for interaction with an anatomical structure in a male penis.

It is respectfully submitted that claims 1-6, 8-25, 32-53, 60-64 and 73-79 do not suffer from obviousness-type double patenting over claims 1-21 of the '670 Patent) in view of DeSushko, or DeSushko in view of Jackson *et al.* (claims 22 and 49). The invention defined in the claims would not have been obvious variations over any invention defined by a claim of the '670 Patent, when the '670 Patent is considered alone or in combination with DeSushko.

The claims of the application are believed to be in condition for allowance. An early action toward that end is earnestly solicited.

Respectfully submitted,

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